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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,374	06/08/2001	Jeffrey C. Rapp	AVI-007N	2448
26739 7590 07/28/2009 Synageva BioPharma Corp. 111 RIVERBEND ROAD ATHENS, GA 30605				
EXAMINER TON, THAIAN N				
ART UNIT		PAPER NUMBER		
1632				
MAIL DATE		DELIVERY MODE		
07/28/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/877,374

Applicant(s)

RAPP, JEFFREY C.

Examiner

Thaian N. Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-29,62-70,72 and 74-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9-29,62-70,72 and 74-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Response, filed 5/15/09, has been entered. Claims 1-5, 9-29, 62-70, 72, 74-76 are pending and under current examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 76 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application".

Applicants' Arguments. Applicants argue that as understood by the practitioner of skill in the art, the feature of claim 76, regarding the antibodies which are produced by the claimed invention being afucosylated is at least inherent in the specification. See p. 2 of the Response.

Response to Arguments. These arguments have been considered but are not found to be persuasive. In particular, MPEP §706.03(o) states that, "In amended cases, subject matter not disclosed in the original application is sometimes added and a claim directed thereto. Such a claim is rejected on the ground that it recites elements without support in the original disclosure under 35 U.S.C. 112, first paragraph." In the instant case, the critical element of the antibody being

afucosylated was not disclosed in the original application, and therefore, does not convey to one of skill in the relevant art that the inventor(s), at the time the Application was filed, recognized this property of the antibodies. See also, MPEP §608.04(a), which states that, "Matter not in the original specification, claims, or drawings is usually new matter. Depending on circumstances such as the adequacy of the original disclosure, the addition of inherent characteristics such as chemical or physical properties, a new structural formula or a new use may be new matter." In the instant case, the specification does not provide adequate written description for the limitations found in claim 76. Thus, claim 76 is found to introduce new-matter into the as-filed disclosure.

To the extent that the claimed compositions and/or methods are not described in the instant disclosure, claim 76 is also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, since a disclosure cannot teach one to make or use something that has not been described.

MPEP §2163.06 notes:

If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph - written description requirement. In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).

MPEP §2163.02 teaches that:

Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application.

MPEP §2163.06 further notes:

When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to

determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure. (Emphasis added).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 9-17, 19-29, 62, 63, 74 and 76 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio et al. when taken with Sanders et al. in further view of Mohammed et al. and in further view of Michael et al. as further evidenced by WO 99/19472 (published April 22, 1999). This rejection is maintained for reasons of record.

Applicants' Arguments. Applicants maintain their arguments regarding the non-obviousness of the rejection in previous responses. Applicants further argue that claim 76 cannot be obvious because none of the cited references mention making an afucosylated antibody, and none of the references put forth a method to make an afucosylated antibody. Applicants argue that since it was unknown that avian oviduct cells produce afucosylated antibodies prior to the present invention, there would be no motivation to combine the cited references to make afucosylated antibodies. Applicants argue that the Examiner has not identified a reason why one of ordinary skill would have combined any prior art elements to arrive at the claimed invention. Applicants argue that the invention clearly yields unexpected results, which results in afucosylated antibodies, and as is understood in the art

contained increased ADCC activity, which would have not been expected prior to the date of filing. See p. 2 of the Response.

Response to Arguments. These arguments are not persuasive. The Examiner has responded to prior arguments in the prior Office actions. Additionally, the Examiner notes that the cited art of record is not commensurate in scope with the claims, and therefore, not commensurate in scope with the unexpected result. In particular, the breadth of the claims is directed to producing a heterologous antibody by any species of avian oviduct cell. Applicants' post-filing art references of Zhu, Raju and Etches are only directed to chicken oviduct cells. Additionally, the cited art of Zhu and Raju of record is post-filing. Nothing in the as-filed disclosure discusses the advantage of using an avian oviduct cell with regard to a lack of fucosylation, therefore there of no support for this in the as-filed disclosure. The increase in potency of monoclonal antibodies was not known at the time of the claimed invention. Given that one of skill in the art would have no knowledge of whether or not fucosylation would produce more potent antibodies, and the fact that the broadest claims do not require the production of an afucosylated antibody, it would have been wholly obvious for one of ordinary skill to combine the cited art to arrive at the claimed invention.

Finally, it is noted that because Applicants' methods are not distinguished from that of the prior art, the combination of art is sufficient to render the claimed invention obvious. That is, there is no unexpected result in the production of a heterologous antibody utilizing an avian oviduct cell. Although the post filing art of Zhu may teach an increased potency in the resultant antibody, there is nothing in the claims that requires this increased potency, the claims merely require production of a heterologous antibody; therefore, the combined art of record would reasonably arrive at the claimed invention. Accordingly, the cited art fails to overcome the prior rejection of record.

The Examiner notes that the cited art of record provides sufficient guidance and motivation to show that one of skill in the art could reasonably arrive at the claimed invention, *i.e.*, producing a heterologous antibody by an avian oviduct cell, with a reasonable expectation of success. If the property of lack of fucosylation and increased potency of the antibody is considered an inherent property, as argued by Applicants, then the combination of art would similarly, and inherently, arrive at this conclusion. The method, as claimed, does not distinguish from the cited art of record, and therefore, would necessarily result in the production of antibodies that lack fucosylation and have increased potency, because the art teaches utilizing the same cells as Applicants' invention. If a property of the avian oviduct cell is such that it does not fucosylate antibodies, then this property would be present in any heterologous antibody produced by an avian oviduct cell.

It is reiterated that the claimed invention is not commensurate in scope with the unexpected result; Applicants have failed to distinguish their methods from those of the combined art, therefore, because the combined art provides the requisite teachings and motivation, it is maintained that this rejection is proper. Although Applicants do not need to recite the advantageous feature of the product that is produced by a method in a particular method claim, because Applicants' method steps result in a heterologous antibody, which is no more than what is taught in the art, the rejection is maintained.

Claim 18 stands rejected under 35 U.S.C. 103(a) as being unpatentable over over Ditullio et al. when taken with Sanders et al. in further view of Mohammed et al. and in further view of Michael et al. as further evidenced by WO 99/19472 (published April 22, 1999), as applied to claims 1-5, 9-17, 19-29, 62, 63 and newly added above, and further in view of Larocca *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Claims 64-70, 72 and newly added claim 75 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ditullio *et al.* when taken Sanders, in further view of Mohammed, and in further view of Michael *et al.* as further evidenced by WO 99/19472 (published April 22, 1999), as applied to claims 1-5, 9-17, 19-29, 62, 63 and newly added claim 74 above, and further in view of Ling *et al.* and Najarfian *et al.*

Applicants provide no substantive arguments with regard to this rejection, other than the traversal of the rejection, as it applies to the arguments addressed above. Accordingly, this rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (571)272-0736. The examiner can normally be reached on 9-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thaian N. Ton/
Primary Examiner, Art Unit 1632